

2014-1648

**United States Court of Appeals
for the Federal Circuit**

ANTARES PHARMA, INC.,

Plaintiff – Appellant,

v.

MEDAC PHARMA INC., and MEDAC GMBH,

Defendants – Appellees.

*Appeal from the United States District Court for the District of Delaware
In Case No. 1:14-cv-00270 Judge Sue L. Robinson*

**PETITION FOR PANEL REHEARING OR
REHEARING *EN BANC* FOR APPELLANT
ANTARES PHARMA, INC.**

Imron T. Aly
Richard J. Hoskins
Sailesh K. Patel
Joel M. Wallace
SCHIFF HARDIN LLP
233 South Wacker Drive
Suite 6600
Chicago, IL 60606
(312) 258-5500

*Counsel for Petitioner
Antares Pharma, Inc.*

DECEMBER 17, 2014

CERTIFICATE OF INTEREST

I, Imron T. Aly, Counsel for Plaintiff-Appellant Antares Pharma, Inc., certify the following:

1. The full name of every party or *amicus* represented by me is:

Antares Pharma, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

The party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

Antares Pharma, Inc. is a publicly traded company. It has no parent corporation and no publicly traded company owns more than 10 percent or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

Imron T. Aly
Richard J. Hoskins
Sailesh K. Patel
Joel M. Wallace
SCHIFF HARDIN LLP
233 South Wacker Drive
Chicago, IL 60606

John C. Phillips, Jr.
Megan C. Haney
Phillips, Goldman & Spence P.A.
1200 North Broom Street
Wilmington, DE 19806

Dated: December 17, 2014

Respectfully submitted,

/s/ Imron T. Aly
Imron T. Aly
SCHIFF HARDIN LLP

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this court: *U.S. Indus. Chem. v. Carbide & Carbon Chem. Corp.*, 315 U.S. 668 (1942); *Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472 (Fed. Cir. 1998); *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991); *In re Hounsfield*, 699 F.2d 1320 (Fed. Cir. 1983).

Further, based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance: does 35 U.S.C. § 251 permit reissue claims for inventions that meet the written description requirement but which were not claimed in the original patent, without additionally requiring that “*the specification* must clearly and unequivocally *disclose* the newly claimed invention *as a separate invention*”? (Slip Op. 15 (emphases added).)

/s/ Imron T. Aly
Imron T. Aly
Attorney of record for Antares

ARGUMENT SUPPORTING PANEL AND *EN BANC* REHEARING

I. Summary of Argument.

Antares seeks rehearing or rehearing *en banc* because the panel incorrectly interpreted the phrase “for the invention disclosed in the original patent” under Section 251. Under the correct interpretation (consistent with 150 years of precedent), an inventor can claim through reissue subject matter disclosed but not claimed in the original patent, provided the disclosure meets the written description requirement. The panel, however, required more, creating a new special rule for reissues, and added a “clearly and unequivocally disclosed” requirement not in the statute, which simply says “disclosed.” The panel apparently based its decision on Supreme Court authority from the 1800s-1940s (before the current Act), without briefing or argument. Respectfully, the Court may benefit from the parties’ submissions before adopting a new “disclosed as a separate invention” test.

Since the 1800s, patentees have used reissues to change *both* specifications and claims, similar to continuation-in-parts today. But because it would be unfair to let inventors use reissues to add new material *to the specification* and then obtain new *claims* related to the new material, the Supreme Court has permitted reissue claims only for the “same invention” disclosed in the “original specification,” in contrast to later-amended *specifications*. Inventors could obtain new and different reissue claims only when supported by the original specification.

Here, however, the panel interpreted the “original patent” requirement contrary to prior precedent, grafting a “super” written description requirement for reissue claims. Under its new standard, “[w]hether or not the written description requirement of § 112 was satisfied . . . the specification must clearly and unequivocally disclose the newly claimed invention *as a separate invention*.” (Slip Op. 15 (emphases added).) The “clearly and unequivocally disclose” requirement contradicts (a) the Supreme Court’s “same invention” requirement and (b) this Court’s previous interpretation of the Act’s “original patent” requirement.

Antares seeks rehearing for this Court to align the “original patent” requirement with precedent concerning the remedial reissue statute. With this realignment, the original patent requirement will be met when there is written description support in the original specification of the original patent.

II. Background

The case is before the Court after the denial of a preliminary injunction. The district court never addressed the original patent rule, instead denying relief after finding that Antares violated the *recapture rule*. The panel did the opposite, skipping the recapture rule and affirming under the original patent doctrine. In so doing, it relied on a slew of Supreme Court cases mentioned in neither party’s briefing. Moreover, it not only affirmed the denial of preliminary injunctive relief,

it also *invalidated the asserted claims* — without permitting fact-finding concerning what the inventor’s disclosures taught one of ordinary skill in the art.

To be sure, there is a doctrinal place for the original patent requirement. The requirement arose because a reissue application can be used to change *both* the specification *and* the claims. Accordingly, to ensure that new *claims* were supported in the *original specification*, it was important to look at the “original patent”—more precisely, the “original specification”—and not the specification in the new patent (which could have been changed), because a proper *reissue* may relate back *only* to the original specification. And that is why Section 251 allows for claiming in reissue anything “*disclosed* in the original patent.” (Emphasis added.) Antares’s reissue claims were allowed because it never changed the *specification*—the claims covered subject matter “disclosed in the original patent.”

Panel or *en banc* rehearing is appropriate because:

- The new “clearly and unequivocally disclosed as a separate invention” test rewrites the statute and contradicts *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991), a decision never overruled *en banc*. Under *Amos*, the “original patent” test is met when the written description test is met, as applied to the original specification.
- Longstanding Supreme Court precedent dictates the same result.
- Under any test, the “original patent” issue presents a factual question, requiring remand rather than the panel decision’s finding of invalidity.

III. The Original Patent Requirement Is Equivalent to the Written Description Test for the Original Specification.

The panel's opinion effectively overruled *Amos*, without *en banc* review. Under *Amos*, the "original patent" requirement is met when Section 112's written description test is met. These "analogous" requirements serve the same purpose.

The *Amos* panel (Mayer, Lourie, Clevenger, JJ.) was pellucid. Under Section 251, a claim satisfies the "original patent" requirement, *unless* "the original specification demonstrates, to one skilled in the art, an *absence of* disclosure sufficient to indicate that a patentee could have claimed the subject matter." 953 F.3d at 618 (emphasis added). Further, it is irrelevant whether or not an invention was "originally claimed" or "an object of the original patent." *Id.* Indeed, not only did *Amos* impose no "disclosed as a separate invention" requirement, it called the original patent test and the written description test "analogous." *Id.* at 617. The difference? The original patent test requires applying the written description requirement to the *original* specification, and not to a later-amended version.

While the panel here relied on *U.S. Indus. Chem. v. Carbide & Carbon Chem. Corp.*, 315 U.S. 668 (1942), *Amos* held that *Indus. Chem.* involved a fact pattern where inventors *added* new matter *to the specification* in the "original patent." 953 F.2d. at 619 n.2. The reissued claims referred to *the new matter* added to the *amended specification*, so those claims were not allowed. *Id.* In contrast, the *Amos* claims had written description support in *the original specification*. *Id.*

Under *Amos*, Antares’s claims are also valid: Antares made no modifications to the specification and added no new matter; the claims found support in the original specification. At a minimum, a remand is required: *Amos* focused on what the specification disclosed “to one skilled in the art,” which is a factual question never adjudicated by the district court. *Id.* at 618.

IV. Supreme Court Precedent from the 1800s Confirms Why the Original Patent Test Means the Written Description in the Original Specification

Amos’s interpretation of *Indus. Chem.* is rooted in long-standing Supreme Court precedent, precedent that also used the “same invention” rule to bar claims that were supported only by disclosure added to the specification during the reissue—not to bar claims supported by disclosure in the original patent. In 1878, the Court carefully discussed the “same invention” rule that the panel here equated with the “original patent” rule. *Giant Powder Co. v. California Powder Works*, 98 U.S. 126, 131 (1878). There, Alfred Nobel first submitted an original patent disclosing a method of making explosives; in a reissue specification, he *added new matter* and new claims regarding a new composition for an explosive. *Id.* at 132. Because the reissued claims referred to the new subject matter, and had “no connection” with the original disclosure, they were held invalid. *Id.* at 137, 139. In interpreting the “same invention” requirement of the 1870 Patent Act, the Court explained that reissued patents could routinely include amended or supplemented specifications, but it was important to trace any reissue *claims* to the original

specification in order to meet the “original patent” rule. *Id.* at 137-38; *see also Gill v. Wells*, 89 U.S. 1, 6 (1874) (“Nothing was said in the original specification to lead one to suppose” the claimed invention had support). The Court stated:

The *specification* may be amended so as to make it more clear and distinct; the *claim* may be modified so as to make it more conformable to the exact rights of the patentee; but the *invention* must be the same. So particular is the law on this subject, that it is declared that ‘*no new matter shall be introduced into the specification.*’

Giant Powder, 98 U.S. at 138 (emphases added). In stating the rationale for the rule, the Court pointed to substantive changes to the specification: “The danger to be provided against was the temptation *to amend a patent so as to cover improvements* which might have come into use, or might have been invented by others, *after its issue.*” *Id.* (emphases added). No such danger exists when, as here, “[t]he specification and claims 1–22 were left unaltered.” (Slip Op. 3.)

For example, in 1887, the Supreme Court applied the *Powder* rule, finding that “there was new substantive matter introduced into the specification of the reissue in the present case,” rendering the claims invalid. *Parker & Whipple Co v. Yale Clock Co.*, 123 U.S. 87, 102 (1887). Because the original specification provided no written description for the reissued claims (the claims were supported ‘only by the *amendments to the specification*’), the Court easily concluded that “[t]here is no evidence of any attempt to secure by the original patent the inventions covered by the first eight claims of the reissue.” *Id.*; *see also Corbin*

Cabinet Lock Co. v. Eagle Lock Co., 150 U.S. 38, 42 (1893) (reissue claims were “not warranted by anything appearing in the original specification”).

In *Yale Lock Mfg. Co. v. James*, 125 U.S. 447, 451 (1888), the Court again faced the question whether a reissue “was not for the same invention as the original patent, *but contained material new matter*, and was therefore invalid.” (Emphasis added.) Quoting at length from the original and later-amended specification, the Court highlighted changes, “[i]n order to [allow] a comparison of the specification and claims of the first reissue with the specification and claims of the original patent.” *Id.* at 454. There, the patentee argued that the “specification of the reissue, although a broader one than was described in the original patent,” still supported the claims. *Id.* at 457. Because the reissued claims relied upon new matter, they could not be obtained. *Id.* at 462-64; *see also Flower v. City of Detroit*, 127 U.S. 563, 571 (1888) (invalid reissue claim related to “new matter introduced into the specification of the reissue” not “indicated or suggested in the original patent”).

In *Topliff v. Topliff*, the Court discussed at length precedent as of 1892, concluding that the “same invention” requirement referred *to the original specification*, and specifically “for the same invention as the original patent, as such invention *appears from the specification and claims of such original*.” 145 U.S. 156, 170 (1892) (emphasis added). *Topliff* upheld broadened reissue claims because the original *claims* “were narrower than the actual invention.” *Id.* at 165,

170. The policy reason for allowing broadening reissues related precisely to the fact that an inventor should be allowed to claim that which was *disclosed* in an original patent: “To hold that a patent can never be reissued for an enlarged claim would be not only to override *the obvious intent of the statute*, but would operate in many cases with great hardship upon the patentee.” *Id.* at 171 (emphasis added).

Against this backdrop, it is clear that *Indus. Chem.* fits the same pattern. There, the specification changed between the original and reissued patent. 315 U.S. at 670-71. The original specification required water, disclosing that the invention involved “the simultaneous action of the oxygen of air and of water in presence of a catalyzer and, if need be, of hydrogen.” *Id.* at 671. In reissue, the *specification was changed* to describe a different reaction, “in causing ethylene to combine directly with molecular oxygen at temperatures of about 150 to about 400 C, in the presence of a surface catalyst.” *Id.* at 674. The reissued *claims*, in turn, relied upon this new disclosure only and *not* the original patent, making straightforward the Court’s application of the by then well-established rule. *Id.* at 676. Although the claims were invalid (lacking as they did support in the original specification), the Court rephrased the test’s language, using “intent” to refer to the original specification: “It must appear from the face of the instrument that what is covered by the reissue was intended to have been covered and secured by the original.” *Id.*

Indus. Chem.’s “intent” language referred to the original *specification* and whether changes to the specification in reissue could effectively “relate back” to that original specification. “The required intention does not appear if the additional matter covered by the claims of the reissue is not disclosed in the original patent.” 315 U.S. at 676. *Amos* recognized that this “intent” language was confusing, but explained that, in any event, “the reissue claims [in *Indus. Chem.*] were invalid because the patentees had added new matter to the original disclosure which was the only support for those claims.” 953 F.2d at 619 n.2.

V. Conflict with Prior Decisions from the Supreme Court and this Court

The panel incorrectly concluded that *Indus. Chem.* imposed a super written description test under which one must “clearly and unequivocally disclose the newly claimed invention *as a separate invention*.” (Slip Op. 15 (emphasis added).) No “disclosed as a separate invention” requirement exists, and for more than 150 years one could claim aspects of inventions that were previously disclosed but not claimed, just as in *Amos*. Indeed, the original patent requirement has always been that claims in a reissue patent must find support in the original patent *specification*, as opposed to a changed or supplemented specification. The panel contravened this precedent, indirectly overruling *Amos*. The Antares patent specification did not change between the original and the reissue, so *Indus. Chem.* did not apply.

As a matter of law, logic, and sound public policy, the written description test is enough. Any attempt to discern between something “disclosed” versus

“clearly and unequivocally disclosed” invites subjective judgment, undermining clarity. Under *Amos*, even the “intent” language in *Indus. Chem.* did not go so far; it was still the written description test because “intent” meant an “objective intent to claim,” a confusing term because it is a “legal oxymoron.” *Amos*, 953 F.2d at n.2; *see also In re Mead*, 581 F.2d 251, 255 (CCPA 1978) (“intent to claim” is a factual inquiry based on the objective intent manifested by the original patent specification); *In re Rowand*, 526 F.2d 558, 560 (CCPA 1975) (same).

Clarifying any doubt, this Court made clear 30 years ago in *Hounsfield* that the original patent test “is analogous to the requirement of § 112, first paragraph.” *In re Hounsfield*, 699 F.2d 1320, 1323 (Fed. Cir. 1983) (citing *In re Mead*, 581 F.2d at 256). “It is, as appellant urges, synonymous with ‘right to claim.’” *Id.* *Hounsfield* also addressed *Indus. Chem.*, explaining that the issue the Supreme Court had faced was whether the original specification disclosed the later-claimed invention, given the intervening amendments to the specification: “[T]he issue before the Supreme Court was whether the reissue patent was for the same invention as the original patent.” *Id.* at 1323. *Hounsfield* invited the Board to focus upon whether the *reissue specification* “contain[ed] disclosure and objects of the invention differing from those of the [original] application.” *Id.* at 1324; *see also In re Peters*, 723 F.2d 891, 894 (Fed. Cir. 1983) (applying 112 standard to 251, and approving reissue claim where “disclosure reasonably conveys to one skilled in the art that the inventor had possession”).

In fact, the *Hester* panel (Plager, Schall, JJ.), credited *Amos* as endorsing a written description test, as opposed to the “intent” language in *Indus. Chem. Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472 (Fed. Cir. 1998). Addressing whether claims “were invalid under the ‘original patent’ clause” and its appropriate test, *Hester* recognized that “[t]his court squarely addressed the issue in *Amos*.” *Id.* at 1484. *Hester* echoed the fact that the original patent inquiry “is analogous to the ‘written description’ requirement.” *Id.* And once again addressing *Indus. Chem.*, *Hester* recognized that whatever the applicability of this pre-1952 Act decision, the case “does not now mandate a separate ‘objective intent to claim’ requirement.”¹ *Id.* at 1485. The “original patent” doctrine was and remained “whether one skilled in the art would identify the subject matter of the reissue claims as invented and disclosed by the patentee.” *Id.* *Hester* recognized that the Court had thrice reached this conclusion: *Amos* “noted that this court reached the same conclusion eight years earlier in *Hounsfield*.” *Id.*

The predecessor CCPA also recognized the “original patent” test as one referring to the original specification. In *In re Handel*, Judge Rich interpreted the 1952 Patent Act and explained that the Board used “the wrong test” for the “original patent” requirement. 312 F.2d 943, 948 (CCPA 1963). The correct test

¹ Although *In re Weiler* also discussed the “intent” language, that decision was based on the error requirement and not the original patent rule. *In re Amos*, 953 F.2d at 619 n.3.

“is to look at the disclosure” of the original patent and determine “whether the claims are for the invention disclosed in the patent.” *Id.* Specifically referring to *Indus. Chem.*, Judge Rich ruled that the “same invention” test meant that “the entire disclosure of the original patent is to be considered in determining what the patentee intended to claim and what invention the patent discloses.” *Id.* Moreover, the whole point of Section 251 is remedial; with a restrictive “same invention” test, “the reissue statute would be of very little practical effect”—by elementary principles, adding or subtracting an element means claiming a different invention. *Id.*

This Court has made expressly clear that reissues can be used to do what Antares did, claim an invention disclosed but not previously claimed: “An inventor’s failure to appreciate the scope of an invention at the time of the original patent grant, and thus an initial intent not to claim the omitted subject matter, is a remediable error.” *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1354 (Fed. Cir. 1998). *Bard* repeated *Amos*’s observation that the “original patent” and the “written description” tests were the same, describing *Amos* as follows: “reissue application not subject to rejection for failure to demonstrate initial intent to claim, when subject matter of reissue claims satisfies § 112 requirements.” *Id.*

And more recently, too, this Court applied the same rule in the same way. In 2009, it held that the “original patent” test was satisfied if the reissue claims found

written description in the original specification. In *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.* (Michel, Bryson, Posner, JJ), it repeated that the “original patent” test “is analogous to the written description requirement.” 563 F.3d 1358, 1367 (Fed. Cir. 2009). In fact, while the accused infringer had argued invalidity under *both* the original patent *and* written description tests, the Court made no separate analysis: “[b]ecause we have held that the written description requirement is satisfied, we similarly hold that claim 22 complies with § 251.” *Id.*

For all these reasons, the panel’s decision incorrectly applied the “original patent” doctrine, and inappropriately created a new, conflicting standard that should be reconsidered and/or the subject of *en banc* review.²

VI. Under Any Standard, a Remand Is at a Minimum Necessary

The district court made no findings under any “original patent” test. Under any test, invalidity should be decided by the fact-finder because unlike the recapture rule (question of law), the original patent test presents a question of fact. *See Amos*, 953 F.2d at 618 (original patent issue “*is an essentially factual inquiry* confined to the objective intent manifested by the original patent”) (emphasis added). Like the written description test, the original patent test asks whether “the original specification demonstrates, to one of ordinary skill in the art” adequate

² Secondary sources also support Antares’s position. *See, e.g.,* Deller’s 1937, quoted in *Patecell v. U.S.*, 16 Ct. Cl. 644, 654 n.3 (Cl. Ct. 1989). In addition, the MPEP, while not binding, aligns with Antares’s position and will need to be rewritten if the panel’s decision stands. *See* MPEP § 1412.01.

disclosure “to indicate that a patentee could have claimed the subject matter.” *Id.*; see also *Battin v. Taggert*, 58 U.S. 74, 84-85 (1854) (“The jury are also to judge...whether the renewed patent is for the same invention as the original patent.”); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (“[written description] inquiry, as we have long held, is a question of fact”). Indeed, Antares is confident that one of ordinary skill in the art would recognize the reissues claims were supported by the original patent specification, because Medac’s own expert admitted this in a deposition. (A867 at 231:4-17, 232:2-13, 233:15-23.) Respectfully, the panel simply overlooked this critical fact, and did not discuss the expert testimony.

Finally, the panel also attempted to distinguish *Amos*, noting that there was an “express” disclosure of the reissue-claimed invention, but did not explain how the *Amos* invention would have met the new “clearly and unequivocally disclosed as a separate invention” test. If express disclosure were enough, there was no dispute that Antares met that requirement because it claimed safety features that *were* expressly disclosed in the specification.

Respectfully submitted,

/s/ Imron T. Aly

Imron T. Aly

Richard J. Hoskins

Sailesh K. Patel

Joel M. Wallace

SCHIFF HARDIN LLP

233 South Wacker Drive
Suite 6600
Chicago, IL 60606
(312) 258-5500

*Attorneys for Plaintiff-
Appellant Antares Pharma, Inc.*

ADDENDUM

**United States Court of Appeals
for the Federal Circuit**

ANTARES PHARMA, INC.,
Plaintiff-Appellant,

v.

MEDAC PHARMA INC. AND MEDAC GMBH,
Defendants-Appellees.

2014-1648

Appeal from the United States District Court for the
District of Delaware in No. 1:14-cv-00270-SLR, Judge Sue
L. Robinson.

Decided: November 17, 2014

IMRON T. ALY, Schiff Hardin LLP, of Chicago, Illinois,
argued for plaintiff-appellant. With him on the brief were
RICHARD J. HOSKINS and SAILESH K. PATEL. Of counsel
was JOEL M. WALLACE.

CHRISTOPHER J. HARNETT, Ropes & Gray LLP, of New
York, New York, argued for defendants-appellees. With
him on the brief were JAMES F. HALEY, JR., CHING-LEE
FUKUDA and HASSEN A. SAYEED.

Before DYK, REYNA, and TARANTO, *Circuit Judges*.

DYK, *Circuit Judge*.

Plaintiff-Appellant Antares Pharma, Inc. (“Antares”) appeals from a decision of the United States District Court for the District of Delaware denying Antares’ motion for preliminary injunction. Antares seeks to enjoin alleged infringement of claims 31, 34, 35, and 37 of a reissue patent, RE44,846 (“the ’846 patent”). Because we hold that these reissue claims are invalid for failure to comply with the “original patent” requirement of 35 U.S.C. § 251, we affirm.

BACKGROUND

I

Antares is a developer of automatic injection devices used to self-administer pharmaceuticals. It is the assignee of U.S. Patent No. 7,776,015 (“the ’015 patent”), which issued on August 17, 2010. That patent, entitled “NEEDLE ASSISTED JET INJECTOR,” discloses a system for injecting medicant in which a needle punctures the skin before forcefully expelling the medicant, thereby minimizing some of the downsides of typical jet injectors (in which the medicant itself ruptures the outer layers of skin), while still maintaining some of the advantages of typical jet injectors. During prosecution, the applicants repeatedly distinguished their invention from the prior art by focusing on the “jet injector” limitation present in their claims but not the prior art. The originally issued claims all contained the “jet injection” limitation.

On June 22, 2012, roughly 22 months after the ’015 patent issued, Antares sought a reissue for the patent pursuant to 35 U.S.C. § 251, stating that there was an error in the original ’015 patent insofar as the patentee claimed “more or less than he had a right to claim in the

patent.” See 35 U.S.C. § 251. Section 251 allows a patent holder to correct an existing, issued patent by broadening or narrowing the originally issued claims. If the claims sought on reissue are broader than the original claims, the patentee must apply for the reissue within two years of the patent issuing. *Id.* Here, the applicants complied with the two-year requirement.

The ’846 reissue patent was granted on April 15, 2014. The specification and claims 1–22 were left unaltered; claims 23–37 were added. The originally allowed claims recite various embodiments of a jet injection device and specify, for example, the exact depth the needle assist plunges to, the force at which the medicant is expelled, and the gauge of the needle. The reissue claims (claims 23–37) cover embodiments of injection devices (not restricted to jet-injection devices) with particular combinations of safety features. Claim 31, for example, covers certain injectors containing at least a latch, pushbutton, and needle guard. By Antares’ own admission, the reissue claims recite a different invention from what was originally claimed. See Appellant Br. 14–15 (“These are two different inventions [Original c]laim 1 is directed to ‘jet injection device’ *performance* [Reissue c]laim 31, on the other hand, is directed to *safety features* for any ‘injection device.’”) (emphasis in original).

II

Defendants medac Pharma, Inc. and medac GmbH (collectively, “Medac”) manufacture and sell pre-filled, hand-powered methotrexate syringes. On September 10, 2013, Medac submitted a 505(b)(2) new drug application (“NDA”) with the FDA for their pre-filled methotrexate syringes, which they intend to sell under the trade name RASUVO. Antares does not accuse the methotrexate medication itself of infringing any patents; rather, Antares accuses the injection device housing the methotrexate

of infringing various claims. Because the product prospectively sold under the application would allegedly infringe claims of the '846 patent, the filing of the application constitutes an act of artificial infringement under 35 U.S.C. § 271(e)(2)(A) (assuming infringement is established).

Antares filed suit against Medac in the District of Delaware on February 28, 2014, initially alleging infringement of certain patents not involved in the present appeal based on Medac's filing of the 505(b)(2) NDA. On March 14, 2014, Antares filed a motion for preliminary injunction. On April 18, 2014, Antares filed an amended complaint, adding the '846 patent to the list of patents it was asserting against Medac, and amended the motion for preliminary injunction accordingly, asserting claims 31, 34, 35, and 37 of the '846 patent. Since only the asserted claims in the '846 patent are at issue on appeal, we limit our discussion to those claims.

On May 5, 2014, Medac counterclaimed for invalidity and non-infringement of the patents-in-suit. On May 28, 2014, Medac filed its opposition to the motion for preliminary injunction, arguing that the asserted reissue claims of the '846 patent were invalid for violating the recapture rule and failing the original patent requirement of § 251. The recapture rule generally prohibits applicants from claiming, on reissue, claim scope surrendered during the course of the original prosecution. *See In re Mostafazadeh*, 643 F.3d 1353, 1358 (Fed. Cir. 2011). As discussed below, the original patent requirement requires that the original specification expressly disclose the particular invention claimed on reissue.

On July 10, 2014, the district court denied the motion for preliminary injunction, finding that Antares failed to carry its burden of showing a likelihood of success on the merits with respect to the '846 patent because claims 31,

34, 35, and 37, added during reissue, are likely invalid for violating the recapture rule. The court found that, during the original prosecution, the applicants repeatedly distinguished the prior art by focusing on the fact that the claims were limited to jet injectors. During reissue, when the applicants sought to claim safety features not limited to jet injectors, they were broadening their claims to cover non-jet injectors. Because the court held that the recapture rule was violated, it did not consider the question of whether the original patent requirement was satisfied. The court held that Antares would likely suffer irreparable harm and that the balance of interests was in equipoise.

Antares appealed the denial of the preliminary injunction with respect to the asserted claims of the '846 patent. We have jurisdiction pursuant to 28 U.S.C. §§ 1292 & 1295. We review the district court's denial of the preliminary injunction for abuse of discretion, but we review errors of law relating to that denial de novo. *Globetrotter Software, Inc. v. Elan Computer Grp., Inc.*, 236 F.3d 1363, 1367 (Fed. Cir. 2001). We review the applicability of the recapture rule and the original patent requirement of 35 U.S.C. § 251 de novo. *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006).

DISCUSSION

I

Antares argues that the district court incorrectly applied the recapture rule and that, under the “overlooked aspects” cases, the recapture rule is inapplicable. In this respect, Antares relies on *Mostafazadeh*, 643 F.3d at 1360. Antares argues that, while the recapture rule generally prohibits a patentee from “regain[ing] through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims,” the recapture rule is entirely inapplicable if the reissue claims

recite “overlooked aspects” of the invention. *Mostafazadeh*, 643 F.3d at 1358 (quoting *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997)); *see also In re Youman*, 679 F.3d 1335, 1347 (Fed. Cir. 2012). Antares argues that overlooked aspects are “patentably distinct (1) inventions; (2) embodiments; or (3) species not originally claimed[,] not mere incidental features of the originally-claimed invention.” *Mostafazadeh*, 643 F.3d at 1360 (citation omitted).¹ Because we hold that the asserted claims of the ’846 patent fail the original patent requirement of 35 U.S.C. § 251, we do not reach the question of whether the recapture rule applies and, if it does, whether it was violated here.

II

Typically, if an applicant files a patent application disclosing and claiming one invention and later realizes that the specification discloses a second or broader invention, he may seek coverage of those additional claims pursuant to 35 U.S.C. § 120, which allows for continuing applications to claim the priority date of earlier applications. One type of continuing application is a continuation application. A continuation application is “a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented.” MPEP § 201.07 (9th ed. Mar. 2014); *see also* 37 C.F.R. § 1.53(b). A divisional application is another type of continuing application and is intended for “distinct invention[s], carved out of a pending application and disclosing and

¹ Antares acknowledges that the “overlooked aspects” cases cannot save separate inventions claimed on reissue but expressly disclaimed during prosecution, because “what was expressly surrendered cannot have been overlooked.” Appellant Rep. Br. at 6.

claiming only subject matter disclosed in the earlier or parent application.” MPEP § 201.06; *see also* 37 C.F.R. § 1.53(b). When an applicant seeks to add new claims pursuant to a continuation or divisional application, the statute explicitly states that the original specification provides adequate support for the new claims if the original specification satisfies the § 112(a) written description requirement for the new claims. 35 U.S.C. § 120.²

The filing of continuations and divisionals is limited by the co-pendency requirement of § 120: a continuing application cannot be filed after the original parent application issues. In such circumstances, an applicant can only seek to add claims by filing a reissue application. 35 U.S.C. § 251. The delay in seeking to broaden the claims is not without cost. By waiting until after the patent is issued, the applicant becomes subject to two additional requirements relevant here: first, the claims must not violate the recapture rule; second, the claims must satisfy the statutory original patent requirement of 35 U.S.C. § 251.³

² These are in contrast to continuations-in-part, which, because they introduce new subject matter, cannot gain the benefit of the earlier filing date for the additional material. MPEP § 201.08.

³ A third requirement, the prohibition on the introduction of “new matter,” restricts applicants’ abilities to modify the specification, rather than the claims, and is not relevant here. 35 U.S.C. § 251 (1952); 35 U.S.C. § 64 (1870); *Gill v. Wells*, 89 U.S. 1, 19 (1874); MPEP § 2163.06–07.

III

The original patent requirement is well-established, being recognized in the reissue statute and longstanding Supreme Court jurisprudence. The current statute governing reissues provides in relevant part:

Whenever any patent is, through error . . . , deemed wholly or partly inoperative or invalid . . . by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall . . . reissue the patent for *the invention disclosed in the original patent*

35 U.S.C. § 251(a) (emphasis added).

Supreme Court cases have recognized this requirement for more than 150 years.⁴ *See, e.g., Battin v. Taggart*, 58 U.S. 74, 85 (1854) (noting that reissued patents must be “for the same invention as the original patent”); *Klein v. Russell*, 86 U.S. 433, 466 (1873) (same). The requirement became even more important when the Supreme Court first held that broadening reissue applications were permissible. *See Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 351, 354–55 (1881) (holding that broadening reissues were permissible under certain circumstances, but that a patentee seeking on reissue to claim a particular configuration of domes relating to lamp technology violated the “same invention” requirement of the reissue statute because the original patent disclosed only a different configuration); *see also In re Staats*, 671 F.3d 1350, 1353–54 (Fed. Cir. 2012) (“Despite the language of the statute referring only to narrowing reissues, the [Supreme] Court . . . held that the statute allowed for

⁴ As discussed below, prior to the 1952 Amendments, the original patent requirement was referred to as the “same invention” requirement.

broadening reissues.”).⁵ Thereafter, the Supreme Court continued to rigorously enforce the original patent requirement. *See, e.g., Topliff v. Topliff*, 145 U.S. 156, 169–70 (1892) (collecting and summarizing cases and noting that reissues “shall be for the same invention as the original patent, as such invention appears from the specification and claims of such original”); *Corbin Cabinet Lock Co. v. Eagle Lock Co.*, 150 U.S. 38, 42–43 (1893) (rejecting reissue claims because they were “merely suggested or indicated in the original specification,” and it was not sufficiently clear that they “constitute[d] parts or portions of the invention”); *Sontag Chain Stores Co. v. Nat’l Nut Co. of Cal.*, 310 U.S. 281, 288 (1940) (“The reissued patent must be for the same invention . . .”).

The Supreme Court’s definitive explanation of the original patent requirement appears in *U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668 (1942). There, the Court analyzed a reissue patent relating to a process for the production of a chemical compound. The original claims required the presence of water as a catalyst. After the patent was issued, it became clear that water was not required as a catalyst. The patentee asserted that the original claim was in error because it required the presence of water, and the patentee sought and obtained a reissue that omitted that “erroneous” requirement. The patentee subsequently brought suit for infringement of the newly added claims, which omitted the water limitation. *Id.* at 670–75. The Court held the reissue claims invalid for failing to satisfy the “same invention” requirement. *Id.* at 680–81. It explained that a reissue claim is for the “same invention” if the original patent specification fully describes the

⁵ This change was codified in the 1952 Amendments. *See* 35 U.S.C. § 251 (1952).

claimed inventions, but not if the broader claims “are [] merely suggested or indicated in the original specification.” *Id.* at 676. “[I]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification.” *Id.* The reissue claims were invalid because, although the original specification hinted at the fact that water might be optional (*see id.* at 672 (“Water can be admitted in the reaction vessel”)), it was nonetheless clear that the invention disclosed in the original patent required the presence of water. *Id.* at 676–78. That hint, suggestion, or indication that water was optional was not enough to save the reissue claims. *Id.* Circuit cases immediately following *Industrial Chemicals* adopted the same test.⁶

The Supreme Court’s articulation of the “same invention” test in *Industrial Chemicals* was in the context of 35 U.S.C. § 64, which had slightly different language from the current reissue statute, 35 U.S.C. § 251. Prior to the 1952 Amendments, the statute provided:

Whenever any patent is wholly or partly inoperative or invalid . . . the commissioner

⁶ See, e.g., *Freeman v. Altvater*, 138 F.2d 854, 859 (8th Cir. 1943) (citing to *Industrial Chemicals* and explaining that “[f]ailing to disclose in the original patent matters claimed in the reissue will not enable the patentee to cover such new matter by the reissue, as least when the matter was within his knowledge when he applied for the original patent[; i]t is not enough that the invention might have been claimed in the original patent or that it was suggested in the specification”); *Monogram Mfg. Co. v. Glemby Co.*, 136 F.2d 961, 963 (2d Cir. 1943) (interpreting *Industrial Chemicals* as asking whether the reissue claims were “fairly disclosed as essential” in the original specification).

shall . . . cause a patent *for the same invention* . . . to be reissued to the patentee

35 U.S.C. § 64 (1946) (emphasis added). The 1952 Amendments changed the language from “the same invention” to “the original patent,” so that the provision reads: “[w]hensoever any patent is, through error . . . , deemed wholly or partly inoperative or invalid . . . the Director shall . . . reissue the patent for the invention disclosed in the original patent” *Id.* § 251 (1952).

Despite the change in language relating to the “same invention” requirement, it appears that no change in substance was intended. There is nothing in the statutory language or legislative history suggesting that Congress intended to overturn the long line of Supreme Court cases culminating in *Industrial Chemicals* by this change in language. As explained in P.J. Federico, *Commentary on the New Patent Act*, reprinted in 75 J. Pat. & Trademark Off. Soc’y 161, 205 (1993):

While the old statute stated that the patent is reissued “for the same invention,” the new statute states that the patent is reissued “for the invention disclosed in the original patent.” Here, again, there is no indication in the printed record that any change was intended, although a slight broadening effect has been argued.⁷

So too, in *Warner-Jenkinson Co. v. Hilton Davis Chemical*, 520 U.S. 17 (1997), although not directly addressing the “same invention” requirement, the Supreme Court explained that “[t]he 1952 Patent Act is not materially

⁷ “Federico’s commentary is an invaluable insight into the intentions of the drafters of the Act.” *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1366 (Fed. Cir. 2002).

different from the 1870 Act with regard to claiming, reissue, and the role of the PTO,” and that “[s]uch minor differences as exist between those provisions in the 1870 and the 1952 Acts have no bearing on [our precedent] and thus provide no basis for our overruling it.” *Id.* at 26.

After the 1952 Amendments, the circuit courts and our predecessor court continued to view *Industrial Chemicals* as articulating the applicable test, irrespective of the passage of the 1952 Amendments. *See, e.g., Bolkcom v. Carborundum Co.*, 523 F.2d 492, 502 (6th Cir. 1975); *McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 389 (10th Cir. 1965); *Riley v. Broadway-Hale Stores, Inc.*, 217 F.2d 530, 531 (9th Cir. 1954); *In re Rowand*, 526 F.2d 558, 559–60 (C.C.P.A. 1975).

Thus, for example, in *McCullough*, the Tenth Circuit held a reissue patent valid over an invalidity challenge. Referencing *Industrial Chemicals*, the court stated that “[t]he original and reissue patents are for the same invention where the latter fully describes and claims the very invention intended to be secured by the original patent and describes and claims only those things which were embraced in that invention and where it is not merely suggested in the original but constitutes a part or portion of that invention.” *McCullough*, 343 F.2d at 389. The court considered that “[i]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification,” but must be “explicitly disclosed and taught” in the specification. *Id.* (internal quotation marks omitted).

Similarly, in *Riley v. Broadway-Hale Stores, Inc.*, 217 F.2d 530, 531 (9th Cir. 1954), the court held that a single, vague reference in the original specification to shoulder pads without gaps in the padding did not adequately support the reissue claims, which claimed shoulder pads without gaps, when the original claims only claimed

shoulder pads with gaps, and the specification described the gapped shoulder pads as an “essential feature” of the invention. *Riley*, 217 F.2d at 532. As the court explained, “[t]he broader claims of the reissue must be more than merely suggested or indicated in the original patent.” *Id.* “[I]t is not enough that an invention might have been claimed in the original invention because it was suggested or indicated in the specification.” *Id.* (quoting *Indus. Chems.*, 315 U.S. at 375–76).

Finally, in *In re Rowand*, our predecessor court rejected a reissue claim seeking coverage of a particular method for making Teflon tubing when the specification focused on describing the product itself. 526 F.2d at 560. The court held that a single, vague statement in the specification broadly summarizing the general method for making Teflon tubing did not adequately disclose the particular method claimed on reissue. *Id.* Citing to *Industrial Chemicals*, the court held that the invention claimed on reissue was not sufficiently disclosed and failed under § 251. *Id.* at 559.

Since the creation of this court in 1982, we have addressed *Industrial Chemicals* and the original patent requirement on four occasions: *In re Hounsfield*, 699 F.2d 1320 (Fed. Cir. 1983); *In re Weiler*, 790 F.2d 1576 (Fed. Cir. 1986); *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991); and *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472 (Fed. Cir. 1998). Significantly, none of those cases suggested that the 1952 change in language worked a substantive change in the “same invention” requirement or that the standard of *Industrial Chemicals* has in any way been altered by the legislative changes. *Hester Industries* simply noted there was a change in the statutory language and that “the essential inquiry under the ‘original patent’ clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the

patentees.” *Hester Indus.*, 142 F.3d at 1484 (quoting *Amos*, 953 F.2d at 618) (ellipsis in original). Similarly, *Amos* noted that *Industrial Chemicals* was decided under the predecessor statute, but nonetheless described the “same invention” requirement as “time-honored.” *Amos*, 953 F.2d at 617, 619 n.2. It dismissed any perceived differences between the two requirements, explaining that the “‘original patent’ clause of § 251” has “historically [been] styled as [the] ‘same invention’” requirement. *Id.*

Our cases shed light on *Industrial Chemicals* in two respects. First, they rejected a gloss put on *Industrial Chemicals* by the Board in later cases, which had interpreted *Industrial Chemical*, *Rowand*, and *In re Mead*, 581 F.2d 251 (C.C.P.A. 1978) as creating an “intent to claim” test for the original patent requirement. In *Hounsfield*, we reversed the Board, holding that the Board’s interpretation put an “erroneous” “gloss” on those decisions. 699 F.2d at 1322–23. The court explained that *Industrial Chemicals*, *Rowand*, and *Mead* merely indicated that “intent to claim” was “only one factor that sheds light upon whether the claims of the reissue application are directed to the same invention as the original patent and the reissue would correct an inadvertent error in the original patent.” *Id.* at 1323; *see also Weiler*, 790 F.2d at 1581 (“Language appearing first in [*Industrial Chemicals*] has been picked up and has metamorphosed into a requirement that an applicant show his original ‘intent to claim’ the subject matter of the reissue claim sought.”). Second, our cases explained that the *Industrial Chemicals* standard is analogous to the written description requirement, which, as our en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) made clear, requires that the patent description “clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Id.* at 1351 (citation and alterations omitted). *See Hester In-*

us., 142 F.3d at 1484; *Amos*, 953 F.2d at 618; *see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1367 (Fed. Cir. 2009) (describing the original patent requirement as “analogous” to the written description requirement).⁸ Whether or not the written description requirement of § 112 was satisfied here, *Industrial Chemicals* made clear that, for § 251, “it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification.” 315 U.S. at 676. Rather, the specification must clearly and unequivocally disclose the newly claimed invention as a separate invention. *Id.*

IV

Applying the *Industrial Chemicals* standard, asserted reissue claims 31, 34, 35, and 37 are invalid. The original claims are significantly different in scope and coverage than the asserted claims. Claims 1–22 are focused on jet injectors, and every one of those claims contains the “jet injection” limitation. The asserted claims are focused on particular safety features and do not contain the jet injection limitation. Indeed, appellants themselves argue

⁸ The court in *Revolution Eyewear* rejected the “original patent” challenge in a single paragraph, ending with the statement that it was doing so “[b]ecause [it had just] held that the written description requirement [was] satisfied.” 563 F.3d at 1367. That statement cannot be taken to establish as precedent that the standards are the same, but merely reflects the way the parties presented the issue, neither of whom made any reference to *Industrial Chemicals* or argued for a standard different than § 112. *See* Opening Brief of Counterclaim-Defendant/Appellant Revolution Eyewear, *Revolution Eyewear*, 2008 WL 4307403, at *29–30 (filed Aug. 18, 2008).

that the asserted reissue claims cover a different invention than that originally claimed. To be sure, the original patent requirement focuses on the original specification rather than the original claims. While the claims may be used to determine whether the written description requirement has been satisfied outside of the reissue context, *Ariad*, 598 F.3d at 1347, by definition in reissue the original claims do not disclose the invention claimed on reissue. Thus, we must look to the specification. The original specification here does not adequately disclose the later-claimed safety features to meet the *Industrial Chemicals* standard. The specification discussed only one invention: a particular class of jet injectors. This is clear from the title of the patent (“Needle Assisted Jet Injector”), the abstract (“A jet injection device. . .”), the summary of the invention (“The present invention relates to a needle assisted jet injector.”), the repetitive descriptions of the “present invention” as being for a jet injector (e.g., “[t]he present invention relates to a needle assisted jet injector,” ’846 patent col. 2 ll. 54–55, and repetitions of “the needle assisted jet injector according to the present invention,” *id.* col. 5 ll 6–7, col. 5 ll 34–35, col. 8 ll. 21–22, col. 12 ll. 34–35, col. 13 ll. 26–27), and the entirety of the specification (“jet” is mentioned 48 times in the 7-page specification).

Although safety features were mentioned in the specification, they were never described separately from the jet injector, nor were the particular combinations of safety features claimed on reissue ever disclosed in the specification. Rather, the safety features were serially mentioned as part of the broader conversation: how to build the patented jet injection device. For example, Antares, in its briefing, emphasizes the “push button” safety feature claimed in the reissue. But, a “push button” is mentioned in only one passage in the specification: “Alternatively, a push button could be located at the proximal end of the

device and be locked in an idle position. The movement of the needle guard could unlock the push button and allow the user to depress it and consequently fire the device.” *Id.* col. 12 ll. 9–13. These “suggest[ions]” or “indicat[ions]” of alternative inventions are not sufficient to satisfy the original patent requirement of § 251. *Indus. Chems.*, 315 U.S. at 676. Nowhere does the specification disclose, in an explicit and unequivocal manner, the particular combinations of safety features claimed on reissue, separate from the jet injection invention. This does not meet the original patent requirement under § 251.⁹

The situation here is quite unlike *Amos*, in which we held that the original patent requirement was satisfied. In *Amos*, the patentee sought to broaden his claims on an invention relating to the use of rollers to hold down workpieces on a moving table. The specification expressly disclosed that rollers, as they approached the end of the table, could be “raised either mechanically by the roller cams or electronically by the computer controlling the router.” *Amos*, 953 F.2d at 614. The original claims only covered the manual embodiment. On reissue, the applicant sought to add the computer-controlled embodiment. *Id.* The Board denied the reissue because there was no objective intent to claim. *Id.* at 615. This court reversed the Board because the exact embodiment claimed on reissue was expressly disclosed in the specification. *Id.* at

⁹ Although the appeal before us is from the denial of a preliminary injunction, whether the claims at issue satisfy the original patent requirement of § 251 does not depend on any not-yet-resolved factual issues, so a remand is not required. See *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1368–69 (Fed. Cir. 2013).

617–19. Such an express disclosure is exactly what was missing here.

CONCLUSION

The claims on appeal are invalid for failure to satisfy the original patent requirement of 35 U.S.C. § 251. Because Antares cannot show likelihood of success on the merits with respect to these claims, the district court properly denied Antares' motion for preliminary injunction.

AFFIRMED

Costs to appellees.

**United States Court of Appeals
for the Federal Circuit**

Antares Pharma Inc. v. Medac Pharma Inc., 2014-1648

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Schiff Hardin LLP, attorneys for Appellant to print this document. I am an employee of Counsel Press.

On the **17th Day of December, 2014**, counsel has authorized me to electronically file the foregoing **PETITION FOR PANEL REHEARING OR REHEARING EN BANC FOR APPELLANT ANTARES PHARMA, INC.** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of the filing to all counsel for the parties registered as CM/ECF users, including any of the following:

Christopher J. Harnett
(Principal Counsel)
Ching-Lee Fukuda
James F. Haley, Jr.,
Hassen A. Sayeed
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036
(212) 596-9000
christopher.harnett@ropesgray.com
ching-lee.fukuda@ropesgray.com
james.haley@ropesgray.com
hassen.sayeed@ropesgray.com
Counsel for Appellees
Medac Pharma Inc., et al.

Two copies will also be mailed to the above principal counsel on this date.

Additionally, sixteen paper copies will be filed with the Court, via Federal Express, on this date.

December 17, 2014

/s/ Robyn Cocho
Robyn Cocho
Counsel Press